

## Message Text

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TO SECSTATE WASHDC 1190

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DEPT PASS TO DR. JAMES KING, HEW, AND R.H. SHELTON, FDA

E.O. 11652: N/A

TAGS: TBIO, OTRA, JA

SUBJECT: VISIT OF FDA OFFICIALS TO PHARMACEUTICAL AFFAIRS BUREAU,

GOJ MINISTRY OF HEALTH AND WELFARE

1. DURING PERIOD JUNE 24-26, T.E. BYERS AND J.A. HALPERIN OF FDA HELD DETAILED AND FRANK DISCUSSIONS WITH SENIOR LEVEL OFFICIALS OF PHARMACEUTICAL AFFAIRS BUREAU (PAB) AND NATIONAL INSTITUTE OF HYGIENIC SCIENCES, LATTER BEING INDEPENDENT RESEARCH AND TESTING ORGANIZATION FUNDED BY MHW.

2. AT PA, SUBJECTS DISCUSSED WERE:

- A. GOOD MANUFACTURING PRACTICES (GMP'S) AND QUALITY CONTROL OF PHARMACEUTICALS.
- B. FREEDOM OF INFORMATION REGULATIONS.
- C. NEW DRUG EVALUATION AND REGISTRATION.
- D. ADVERSE REACTION REPORTING SYSTEMS.
- E. IMPACT OF SEN-KENNEDY'S HEARINGS ON DRUG REGULATION (AT INSISTENCE OF JAPANESE).

3. DISCUSSIONS INCLUDED DETAILED DESCRIPTIONS OF OPERATIONS OF RESPECTIVE AGENCIES IN AREAS 2A-D ABOVE AND JAPANESE ASKED CAREFULLY PREPARED, PROBING QUESTIONS TO WHICH FULL RESPONSES WERE GIVEN OR PROMISED IN WRITING. JAPANESE IN TURN RESPONDED TO US QUESTIONS AS FULLY AS COULD HAVE BEEN EXPECTED. BOTH SIDES AGREED THAT DIRECT COMMUNICATION CHANNEL BE ESTABLISHED BETWEEN FDA AND PAB FOR ROUTINE EXCHANGES OF SCIENTIFIC AND REGULATORY INFORMATION.

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EMBASSY AGREES WITH THIS APPROACH AS METHOD OF INSURING THAT

INFORMATION OF PUBLIC HEALTH SIGNIFICANCE IS RECEIVED PROMPTLY BY EACH SIDE. EXCHANGES INVOLVING POLITICAL OR OTHER SENSITIVE MATTERS WILL CONTINUE TO FLOW THROUGH DIPLOMATIC CHANNELS.

4. PAB OFFICIALS CAUTIOUSLY RAISED SUBJECT OF FORMAL INTERAGENCY AGREEMENT OF TYPE NOW IN EFFECT BETWEEN FDA AND SWEDISH DEPARTMENT OF DRUGS. US SIDE RESPONDED THAT MATTER WARRANTED FURTHER EXPLORATION AND BOTH SIDES AGREED TO PURSUE MATTER IN MORE DETAIL IN NEXT FEW MONTHS. EMBASSY COMMENT: QUESTION OF WHETHER ANY FORMAL ARRANGEMENT FOR COOPERATION SHOULD BE AT INTERAGENCY OR GOVERNMENTAL LEVEL SHOULD BE CONSIDERED BY DEPARTMENT AND DHEW IN TERMS OF OTHER MEDICAL AND SCIENTIFIC COOPERATION AGREEMENTS NOW IN FORCE.

5. NOTWITHSTANDING ATTEMPTS TO DETERMINE WHY JAPANESE PURSUED SUBJECT OF KENNEDY HEARINGS SO VIGOROUSLY, US REPS WERE UNSUCCESSFUL IN ELICITING A MEANINGFUL RESPONSE. HOWEVER, US REPS DID ANSWER QUESTIONS ABOUT HEARINGS, WHICH RANGED OVER INVESTIGATION OF PROMOTION OF PHARMACEUTICALS, THE "DRUG LAG", AND KENNEDY INVESTIGATION OF PERFORMANCE OF FDA.

6. AT INSTITUTE OF HYGIENIC SCIENCES, DIRECTOR AND STAFF PRESENTED DETAILED EXPOSITION OF LABORATORY OPERATIONS, INCLUDING INTERESTING WORK BEING DONE ON MUTAGENICITY. DR. IWAO KAWASHIRO, DIRECTOR OF INSTITUTE, WILL BE VISITING US IN SEPTEMBER, AND EXPECTS TO VISIT DHEW AND FDA. HE WAS ASSURED OF USG INTEREST IN SUCH A VISIT AND WAS OFFERED ASSISTANCE IN MAKING ARRANGEMENTS.

7. ATMOSPHERE DURING ENTIRE BYERS AND HALPERIN VISIT WAS EXTREMELY CORDIAL, INCLUDING LESS FORMAL CONTACTS WITH PHARMACEUTICAL COMPANY REPRESENTATIVES.  
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## Message Attributes

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